REMARKS

I.   OVERALL REVIEW

Claims 1, 3-7, 9-16, 18, 19, 21 and 23-31 remain pending after entry of this amendment. Claim 8 has been cancelled. Applicants respectfully request that this amendment be entered because it places claims in condition for allowance. Favorable reconsideration is respectfully requested in light of the amendments and remarks submitted herein.

Applicants note that the objection claim for priority on page 1 of the specification has been withdrawn.

Applicants also note that objection to the specification for failing to comply with 37 CFR §§ 1.821-1.825 has been withdrawn.

Applicants further note that the objections of claims 20-22 have been withdrawn.

II.   CLAIM REJECTIONS – 35 U.S.C. § 112

A.   35 U.S.C. § 112, second paragraph

Claims 1, 3-8, 14-16, and 18 remain rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, for the reasons of record stated in the Office Action mailed July 1, 2003. Claims 1 and 14 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 1 was rejected because the recitation, "is expressed primarily under heat shock conditions" made it unclear whether the isolated nucleotide sequence also comprises a heat shock promoter. The Examiner states that the rejection was questioning if the native nucleotide

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sequence encoding it is induced under heat shock condition. Further the Examiner states that the recitation is supposed to be characterizing the protein, not the nucleotide sequence. The Examiner states as it is clear that one skilled in the art may attach any desirable, isolated promoter to any isolated nucleotide coding sequence, it was not clear how the recitation was further characterizing the regulatory protein.

The Office Action alleges that the phrase "is expressed under heat shock conditions" is indefinite. Applicants respectfully disagree regarding the indefiniteness of the quoted passage. The Board of Patent Appeals and Interferences has stated:

> In rejecting a claim under the second paragraph of 35 U.S.C. § 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *Ex parte* Wu, 10 USPQ 2d 2031, 2033 (B.P.A.I. 1989)(citing *In re* Moore, 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971); *In re* Hammack, 427 F.2d 1380, 166 USPQ 204 (C.C.P.A. 1970)).

The M.P.E.P. adopts this line of reasoning, stating that:

> The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:
>
> (1)   The content of the particular application disclosure;
> (2)   The teachings of the prior art; and
> (3)   The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *M.P.E.P.* § 2173.02.

Applicants respectfully submit that the claim language in question, when analyzed in light of the content of the application disclosure, is not indefinite. The specification, at pages 15-16, states that "[t]he term expression refers to the biosynthesis of a gene product. Structural gene expression involves transcription of the structural gene into mRNA and then translation of the

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mRNA into one or more polypeptides." Further, one possessing ordinary skill in the art would know that expression is the process by which a nucleic acid sequence encoding information is translated into a protein, unless it is transfer or ribosomal RNA.

Nonetheless, in order to expedite prosecution, Applicants have amended claims 1 and 14 so that they now recite a protein characterized by the following "is expressed natively under heat shock conditions." Applicants respectfully submit that amended claims 1 and 14 have overcome Examiner's rejection, and that claims 1 and 14 are in condition for allowance.

The Examiner rejected claim 14 as indefinite because the last recited method step was inconsistent with the preamble. The Examiner states that the last amendment only indicates that transgenic plants are regenerated from the transformed plant cells. The Examiner states that the last step does not resolve an increase in plant tolerance to heat and drought. The Examiner suggested that the recitation, --, wherein expression of said protein in the transgenic plant increases heat and drought tolerance -- be inserted in the last line after "cells". Applicants thank Examiner for the suggested language and has accordingly modified claim 14. Claim 14 now recites "regenerating a transgenic plant from said transformed cells wherein expression of said protein in the transgenic plant increases heat and drought tolerance." Applicants respectfully submit that amended claim 14 has overcome Examiner's rejection, and that claim 14 is in condition for allowance.

Amended claim 1 is definite. Claims 3-7 dependent on amended claim 1 are now believed to be definite. Similarly, independent amended claim 14 is definite. Claims 15-16 and 18 dependent from claim 14 are likewise definite. In view of the amendments to claims 1 and 14, Applicants believe that claims 1, 3-7, 14-16 and 18 are now allowable.

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B.   **35 U.S.C. § 112, first paragraph**

Claims 1, 3-8, 14-16, 18, 21 and 23-31 remain rejected under 35 U.S.C. § 112, first

paragraph, as failing to comply with the written description requirement. The Examiner states

that the claims contain subject matter which was not described in the specification in such a way

as to reasonably convey to one skilled in the relevant art that the inventors at the time that the

application was filed had possession of the claimed invention, for the reasons of record stated in

the Office Action mailed July 1, 2003. The Examiner states that the claims do not recite any

function for the nucleotide sequence or the regulatory protein it encodes. The Examiner states

that the claim encompasses nucleotide sequences that can have any function, including those that

are not described in the specification and not possessed by SEQ ID NO:6.

Examiner states that Applicants need to recite a function for nucleotide sequence or the

regulatory protein that it encodes. In its Guidelines, the PTO has determined that the written

description requirement can be met by showing that the invention is complete by disclosure of

sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, or

other physical and/or chemical properties, functional characteristics when coupled with a known

or disclosed correlation between function and structure, or some combination of characteristics.

Guidelines, 66 Fed. Reg. at 1106. Thus, under the Guidelines, the written description

requirement would be met for claims if the specification discloses a nucleic acid which encodes a

protein with a specific activity. See Example 9, Guidelines, at pages 35-37. See Application of

Guidelines, available at http://www.uspto.gov/web/patents/guides/htm, (Application of

Guidelines, Example 9, at pages 35-37).

Accordingly, claim 1 has been amended to recite "a protein characterized by the

following: ... wherein expression of said protein increases heat and drought tolerance in plants."

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The written description requirement is met for claims if the specification discloses a nucleic acid which encodes a protein with a specific activity. In the instant invention, the specification discloses a nucleic acid, SEQ ID NO:6. This nucleic acid sequence (SEQ ID NO:6) encodes elongation factor protein, EF-Tu and has been used to identify at least three heat shock proteins with homology to protein chloroplast elongation factor EF-Tu. Specification, at page 10. See also SEQ ID NOs: 1, 4, and 5. The proteins have been shown to have a specific activity. In particular, the proteins have molecular chaperone activity and thermal protection activity. See Patent Application Update, Figure 2 showing thermal aggregation studies involving the stabilization of a heat labile enzyme by recombinant EF-Tu encoded by SEQ ID. NO:6. Further, the expression of the EF-Tu protein correlates with an increase in heat and drought tolerance *in vivo*. Specification, at pages 51-52, example 6 provides evidence that maize hybrid plants containing increased levels of EF-Tu have increased resistance to heat and tolerance to stress.

Thus, since the specification discloses a nucleic acid which encodes a protein with a specific activity, the claimed invention is adequately described.

Claim 1 has been amended to recite the function "wherein expression of said protein increases heat and drought tolerance in plants." Claims 3-7 dependent on amended claim 1 are now believed to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. Similarly, independent claim 14 has been amended to recite the function "wherein expression of said protein in said transgenic plant increases heat and drought tolerance." Claims 15, 16, and 18 dependent from claim 14 are now believed to comply with the written description requirement under 35 U.S.C. § 112, first paragraph. In view of the amendment to claims 1 and 14, Applicants believe that claims 1, 3-7, 14-16, 21, and 23-31 are now allowable.

C.   35 U.S.C. § 112, first paragraph

Claims 1, 3-8, 14-16, 18, 21, and 23-31 remains rejected under 35 U.S.C. § 112, first

paragraph, as failing to comply with enablement requirement. The Examiner states that the claim

contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention, for the reasons of record stated in the Office Action mailed July 1,

2003. The Examiner states that Applicants' arguments were fully considered but were not found

persuasive. The Examiner states that Applicants argue that the specification indicates that the

method for isolating other polynucleotides are known to those of skill in the art would typically

be based on screening for other plants with heat and drought tolerance and which express EF-Tu

during stress. The Examiner states however methods of isolating a nucleotide sequence are not

methods of making it. See Bayer AG v. Housey Pharmaceuticals, Inc., 68 U.S.P.Q.2d 1001

(CAFC, 2003), at page 1009 where it states, "we agree with the District Court's conclusion that

the process of identification and generation of data are not steps in the manufacture of a final

drug product."

Applicants respectfully point out that the term "isolated" was intended to include isolation

as a first step towards sequencing and identifying other similar sequences. Applicants

respectfully disagree and point out that Bayer A.G. v. Housey Pharmaceuticals has application

under 35 U.S.C. § 271(g) and is not applicable to 35 U.S.C. § 112 rejections. The issue in

Housey was whether infringement under 35 U.S.C. § 271(g) occurs when a product made

overseas by a United States patented process is then imported into the United States. Housey,

340 F.3d 1367 (Fed. Cir. 2003). The holding of Housey is that section 271(g) only protects

manufactured physical products covered by the claims of the United States patent. Housey, 340

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F.3d at 1367. The court in Housey did not address the issue of whether the "processes of identification and generation of data are not steps in the manufacture of a final drug product" under 35 U.S.C. § 112, nor has Congress amended § 112 to state that methods are not enabling unless pertaining to manufactured physical products.

The Examiner states that Applicants argue, in response to the issue that the specification does not teach that all EF-Tu proteins increase heat and drought stress in plants, that certain passages on pages 7 and 11 of the specification teach that the EF-Tu can be of any family of 45kD heat shock proteins including SEQ ID NOs: 1-3, and those substantially equivalent thereto, and that synthesis of chloroplast EF-Tu stabilizes plants during stress. The Examiner states however the specification teaches that multiple 45kD heat shock proteins were synthesized in the chloroplast of the heat and drought tolerant maize line ZPBL 1304, with the protein encoded by SEQ ID NO: 6 being just one. The specification does not show that the transgenic plants expressing only SEQ ID NO:6 have increased drought and heat tolerance.

Applicants traverse this rejection. Applicants respectfully direct the Examiner's attention to MPEP § 2164 et seq. This section provides that Examiner must make a *prima facie* case in order to maintain a rejection of nonenablement with respect to the disclosure of a patent application under 35 U.S.C. § 112, first paragraph:

1. a rational basis as to
    a. why the disclosure does not teach, or
    b. why to doubt the objective truth of the statements in the disclosure that purport to teach;
2. the manner and process of making and using the invention;
3. that correspond in scope to the claimed invention;
4. to one of ordinary skill in the pertinent technology;
5. without undue experimentation; and
6. dealing with subject matter that would not already be known to the skilled person as of the filing date of the application.

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Since the Examiner has not provided evidence supporting each of these elements, the

Examiner has not made out a *prima facie* case for nonenablement under 35 U.S.C. § 112, first

paragraph.

Further, Applicants respectfully submit that the specification does provide enablement

commensurate with the scope of claims 1, 3-7, 14-16, 18, 21, and 23-31 for the following

reasons. Applicants have demonstrated an association between heat resistance and the isolated

EF-Tu. First, Applicants' specification at page 15 describes the identification of trait that is

inheritable from maize and confers heat and drought resistance. Several heat shock proteins (EF-

Tu) of 45kD from these heat and drought resistant plants were identified, isolated, and purified.

Specification, at page 15, lines 4-13. Specification, Example 3, pages 40-50. The amino acid

sequence of these proteins is provided in Table 2, as SEQ ID NO:1, SEQ ID NO:4, and SEQ ID

NO:5. Plants that were heat and drought tolerant produced the 45 kD EF-Tu.

Second, methods for isolating proteins sharing homology with EF-Tu and the

corresponding nucleotide sequences encoding the EF-Tu are known to those of skill in the art.

Specification, at pages 18, lines 12-18 describes the screening of prokaryotic and eukaryotic

organisms for other isoforms of EF-Tu proteins and Example 4, at page 50, describes the

identification of maize EF-Tu ESTs from use of EF-Tu peptide sequences. Applicants

respectfully point that this method was successfully employed to obtain three heat shock proteins

(EF-Tu). Specification, at page 15, lines 10-13.

Similarly, the expression of these sequences in plants can be manipulated by one skilled

in the art. For example, the specification, at page 16, lines 14-17 and lines 29-31 and Table 1

Promoter Expression Summary, describes controlling the spatial or temporal expression of the

EF-Tu by employing different regulatory elements, such as enhancers or promoters that are

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known to one skilled in the art. Applicants also describe methods necessary for making a transgenic plant expressing the EF-Tu sequence. The specification describes numerous methods for plant transformation, such as agrobacterium-mediated transformation, direct gene transfer, microprojectile-mediated transformation, and sonification of target cells. Specification, at pages 28-30. In addition, Applicants also refer one skilled in the art to published protocols. Specification, at pages 27-28, referencing Miki et al., "Procedures for Introducing Foreign DNA into Plants" in Methods on Plant Molecular Biology and Biotechnology, Glock, B.R. and Thompson, J.E. Eds. (CRC Press, Inc., Boca Raton, 1993).

Third, Applicants have further demonstrated an association between increased levels of chloroplast protein synthesis elongation factor EF-Tu and drought and heat tolerance in plants. Specification, at page 15, lines 22-24. See specification, at pages 51-52, Figure 6, providing evidence that maize hybrid plants containing increased levels of EF-Tu have increased resistance to heat and tolerance to stress. These portions of the figures and specification, among others, enable a person of ordinary skill in the art to make and use the invention commensurate with the scope of claims 1, 3-7, 14-16, 18, 21, and 23-31.

Claim 7 stands rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that in response to the issue that claim 7 encompasses non-plant eukaryotic host cells. Applicants argue that the specification teaches that Example 5 teaches the expression of EF-Tu and *E coli*. The Examiner states however that the rejection raised the issue of lack of enablement of non-plant eukaryotic host cells, and the Office Action suggestion limiting claim 7 to bacterial and plant host cells. Applicants have amended the claim with bacterial and plant host cells, thereby alleviating the § 112 first paragraph rejection.

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III.   CLAIM REJECTIONS- 35 U.S.C. § 102(b)

Claim 1 remains rejected under 35 U.S.C. § 102(b) as being anticipated by Muryama et

al. (Plant Mol. Biol. 1993, Vol. 22, pages 767-774), for the reasons of record stated in the Office

Action mailed July 1, 2003. The Examiner states that Applicants traverse the rejection in the

paper submitted September 29, 2003. The Examiner states that Applicants' arguments were fully

considered but were not found persuasive.

The Examiner states that the property of being expressed under heat shock conditions, is

inherent to the protein, absent evidence to the contrary. The Examiner further states that

discovery of a new role or property of a prior art product does not make that protein patentable.

The Examiner states that nucleotide sequence disclosed in the reference can hybridize to instant

SEQ ID NO:6 under conditions equivalent to those recited in claim 1 is a property that is also

inherent to the sequence. The Examiner states that the structure of the nucleotide sequence

disclosing the reference is not changed by any newly discovered role or property.

Claim 1 as amended recites: "[a] purified and isolated nucleotide sequence said

nucleotide sequence having at least 80% homology to the sequence of SEQ ID NO:6." This

amendment is supported in the specification, at page 11, second full paragraph. Applicants

respectfully submit that the Murayama reference does not teach the element "nucleotide sequence

having at least 80 % homology to the sequence of SEQ ID NO:6." Using the NCBI Blast

program available at www.ncbi.nlm.nih.gov/blast shows that SEQ ID NO:6 has 77% and 74%

identity with the nucleotide sequences under GenBank accession numbers D11375 and D11376

respectively, the sequences cited in Murayama. (Please find BLAST results attached with

response.) Specification, at page 11, describes the calculation of homology by standard methods

which involve aligning two sequences to be compared so that maximum matching occurs, and

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calculating the percentage of those matches. Applicants did not present these BLAST results

earlier because claim 1 as initially presented was not believed to be anticipated by Murayama.
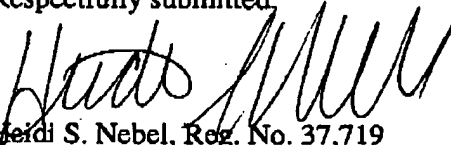
Thus, the Murayama reference does not teach each element of amended claim 1 because

the nucleotide sequences being described by the Murayama reference and the instant invention

have less than 80% homology. Therefore, claim 1 is not anticipated by Murayama. In light of

the amendment to claim 1, Applicants believe that claim 1 is in condition for allowance.

IV.   CONCLUSION

In light of the above remarks, Applicants respectfully assert that claims 1-7, 14-18 and

20-31 are now in condition for allowance. Applicants respectfully request reconsideration and

withdrawal of the above rejections.

No fees or extensions of time are believed to be due in connection with this amendment;

however, consider this a request for any extension inadvertently omitted, and charge any

additional fees to Deposit Account No. 26-0084.

Respectfully submitted,

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Attorneys of Record

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Blast 2 Sequences results

PubMed   Entrez   BLAST   OMIM   Taxonomy   Structure

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.9 [May-01-2004]

Match: $\boxed{1}$ Mismatch: $\boxed{-2}$ gap open: $\boxed{5}$ gap extension: $\boxed{2}$

x_dropoff: $\boxed{50}$ expect: $\boxed{10.000}$ wordsize: $\boxed{11}$ Filter ☑ $\boxed{\text{Align}}$

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Sequence 2 lcl|seq_2 Length 1680 (1 .. 1680) *Ristic sequence*
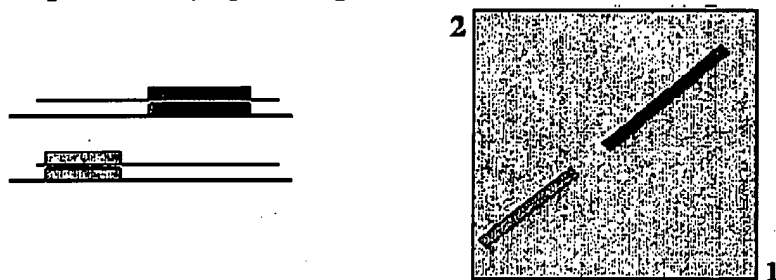
NOTE: The statistics (bitscore and expect value) is calculated based on the size of nr database

NOTE: If protein translation is reversed, please repeat the search with reverse strand of the query sequence

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Identities = 444/597 (74%)
 Strand = Plus / Plus
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Gapped
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